

**United States Senate**  
WASHINGTON, DC 20510

October 21, 2020

The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services (HHS)  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Azar:

We write on behalf of the estimated 5.8 million Americans currently living with Alzheimer's disease.<sup>1</sup> Beyond the individual cognitive decline and vast psychological and emotional consequences for families, the costs to society of Alzheimer's disease are staggering. For instance, a 2013 study funded by the National Institute on Aging (NIA) estimated the total annual cost of dementia in the United States to lie between \$159 billion and \$215 billion, with that figure projected to grow to between roughly \$379 billion and \$511 billion by 2040.<sup>2</sup> Moreover, after adjusting for an individual's underlying health conditions and demographics, the same study estimated the annual cost of informal caregiving attributable to dementia to range between \$13,188 and \$27,789 per person.<sup>3</sup> For Medicare, the nation's largest public health care payer, dementia-specific costs imposed an additional \$2,752 per person on the program.<sup>4</sup>

Nearly a decade later, much work remains to address the momentous societal costs of Alzheimer's disease and related dementias. Currently, pharmacological interventions are unable to cure or even effectively treat the relentless progression of Alzheimer's disease.<sup>5</sup> Congress has long recognized the challenges facing Alzheimer's disease patients and their families, and in 2011, passed the *National Alzheimer's Project Act* (P.L. 111-375; NAPA).<sup>6</sup> This landmark legislation put forth the laudable goal of finding a cure and treatment by 2025.

As the Chair and Ranking Member of the Senate Committee on Finance Subcommittee on Health Care, we are committed to advancing efforts to meet the goals set forth in NAPA as well as improving care for existing and future patients. In February, we published a request for information from experts and stakeholders to inform our regulatory and legislative efforts. Specifically, we inquired about mechanisms that could promote care coordination for Alzheimer's disease patients enrolled in federal health programs, improve disease detection, enhance the affordability and accessibility of long-term care, strengthen protections for

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<sup>1</sup> Alzheimer's Association – 2020 Report: <https://alz-journals.onlinelibrary.wiley.com/doi/epdf/10.1002/alz.12068>.

<sup>2</sup> Monetary Costs of Dementia in the United States: <https://www.nejm.org/doi/full/10.1056/nejmsa1204629#:~:text=We%20found%20that%20dementia%20leads, costs%20per%20adult%20by%202040>.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Alzheimer's Association – Treatments: <https://www.alz.org/alzheimers-dementia/treatments#:~:text=While%20there%20is%20no%20cure, and%20improve%20quality%20of%20life>

<sup>6</sup> P.L. 111-375: <https://www.congress.gov/111/plaws/publ375/PLAW-111publ375.pdf>

vulnerable individuals, and incentivize the development of cures. In response, we received 36 comment letters comprised of more than 200 policy recommendations. Today, we are asking you to review a subset of these recommendations and take specific actions to make progress toward these important goals.

## **RECOMMENDATIONS**

### **PROMOTE COORDINATED, QUALITY CARE**

- 1. Develop New Demonstration Projects:** We encourage the Centers for Medicare & Medicaid Services (CMS) or the Center for Medicare & Medicaid Innovation (CMMI) to create and test alternative payment and coordinated care models targeted toward Medicare and/or Medicaid beneficiaries with Alzheimer's disease that would improve care coordination, reduce duplicative service utilization, and increase the quality of care.
- 2. Develop Quality Indicators for Dementia Care Services:** To ensure quality of care for enrollees in federal health programs, we encourage CMS to assess the state of quality indicators for dementia care services. Alzheimer's disease patients often utilize a variety of services such as adult day programs, meal and transportation services, and memory care centers. Yet, CMS has not produced clear guidance for state Medicaid programs and Medicare Advantage plans on what measures are meaningful for Alzheimer's disease patients' health outcomes and quality of care. Similarly, new quality measures for Programs of All-Inclusive Care for the Elderly (PACE) organizations could allow patients and their caregivers to make more informed decisions. In a February 2020 report, the National Quality Forum's Measure Application Partnership encouraged CMS to prioritize measure development for this patient population. We urge HHS and CMS to review existing quality reporting programs and other payment systems in which quality reporting is lacking within the Medicare and Medicaid programs. Moreover, we urge HHS to establish a plan to implement specific quality care indicators for services heavily utilized by Alzheimer's disease patients.
- 3. Issue Guidance for Comprehensive Care Practices:** In 2019, the NAPA Advisory Council recommended that HHS form a working group to determine best care practices for Alzheimer's disease patients.<sup>7</sup> We urge HHS to quickly implement this recommendation, and once identified, work with the relevant agencies to issue guidance to health plans and providers detailing these practices.
- 4. Increase Coordination of Care Planning:** CMS is reviewing comments from stakeholders regarding wider adoption of interoperable health information technology (IT) systems across long-term care settings.<sup>8</sup> Inclusion of items, such as a patient's care plan, could enhance care coordination of health and social services that support cognitively impaired individuals. We recommend that CMS continue to work with providers, patients, and their caregivers to facilitate mobility of this information across care settings. Encouragement from CMS of documenting in a patient's medical record the

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<sup>7</sup> NAPA Advisory Council – 2019 Recommendations: <https://aspe.hhs.gov/public-member-advisory-council-alzheimers-research-care-and-services-2019-recommendations>

<sup>8</sup> CMS – Interoperability and Patient Access Final Rule: <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

name of a family member or caregiver, as well as any advance directives, could also improve care coordination.

5. **Review Patient Access to Palliative Care:** Palliative care encompasses a set of services that provide medical, social, emotional, and practical support for people living with serious illness.<sup>9</sup> Several of our stakeholders expressed their support for expanding coverage and access to palliative care in federal health programs, including traditional Medicare, Medicare Advantage, and Medicaid. We encourage CMS to review current access to palliative care and report to Congress on areas such as provider prevalence, cost, and quality of care.
6. **Create a Nursing Home Staff Database:** Nursing home medical directors play an important role in the coordination and quality of care for patients with Alzheimer's disease residing in long-term care facilities. We urge CMS to establish and operate a publicly available database for nursing home medical directors so that families and caregivers have a reliable source of contact. Such a database could be posted to the CMS website in a similar fashion to how CMS posts Medicare Part D contact information.<sup>10</sup>

## LEVERAGE TELEHEALTH SERVICES

1. **Revise the Limit on Billable Telehealth Visits for Nursing Care Facilities:** Currently, CMS allows just one telehealth visit every 30 days in nursing care facilities.<sup>11</sup> Several of our stakeholders argue that this policy is arbitrary and limits access to care for patients living with Alzheimer's disease in institutional settings. CMS has attempted to address this concern by revising the limit to once every three days in its proposed physician fee schedule rule for calendar year 2021.<sup>12</sup> CMS has also noted the potentially greater acuity and complexity of Medicare beneficiaries in nursing care facilities, as well as the importance of in-person care in that context.<sup>13</sup> We find access to telehealth in this setting to be important to the care provided to Alzheimer's disease patients, and we support CMS efforts to expand telehealth access across settings where clinically appropriate and with adequate beneficiary protections in place.

## STRENGTHEN THE PACE PROGRAM FOR ALZHEIMER'S DISEASE PATIENTS

1. **Implement Congressionally-Intended PACE Pilot Demonstrations:** In 2015, the *PACE Innovation Act* (P.L. 114-85)<sup>14</sup> authorized CMMI to test the PACE model for new populations with complex and special needs. Rather than test PACE-specific models, however, CMMI has requested PACE organizations (POs) apply to a separate Direct Contracting model focused on primary care. In a Senate Committee on Finance Report,<sup>15</sup>

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<sup>9</sup> NIA – What Are Palliative Care and Hospice Care: <https://www.nia.nih.gov/health/what-are-palliative-care-and-hospice-care#palliative>

<sup>10</sup> CMS – Part D Contacts: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDContacts>

<sup>11</sup> CMS – Revisions to Part B for CY 2012: <https://www.federalregister.gov/documents/2011/11/28/2011-28597/medicare-program-payment-policies-under-the-physician-fee-schedule-five-year-review-of-work-relative>

<sup>12</sup> CMS – CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies: <https://www.federalregister.gov/documents/2020/08/17/2020-17127/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>

<sup>13</sup> Ibid.

<sup>14</sup> P.L. 114-85: <https://www.congress.gov/114/plaws/publ85/PLAW-114publ85.pdf>

<sup>15</sup> S. Rept. 114-108: <https://www.congress.gov/congressional-report/114th-congress/senate-report/108/1>

the Committee stated the intent of the legislation was to test changes to the PACE model, either through an expansion of eligibility standards and/or changes to administrative requirements that would enable greater enrollment. Based on stakeholder information we have received, we believe the existing Direct Contracting model does not provide the flexibility necessary to test PACE-specific models. We request that CMMI follow the intent of the statute to create a PACE-specific model.

2. **Improve the PACE Application Process:** By law, PACE-eligible individuals must reside in the service area of their applicable PACE program.<sup>16</sup> Moreover, CMS only reviews service area expansion applications on a quarterly basis and POs are limited to one pending application under CMS review at a time.<sup>17,18</sup> Thus, we request that CMS review PACE service area expansion applications more frequently and allow POs to submit more than one service area expansion application at a time. Furthermore, CMS must prioritize timely review of service expansion applications and other updates to the program to ensure the federal government is not a barrier to access for individuals who may benefit from PACE enrollment.

## **CONSOLIDATE RESOURCES FOR CAREGIVERS AND PATIENTS**

1. **Establish a Centralized, Alzheimer's Disease-Specific Portal for Patient and Caregiver Resources:** Patients living with Alzheimer's disease, along with their caregivers, must often navigate a series of complex decisions involving long-term care planning and the various institutional or community-based services available to them. Currently, HHS, its agencies, and state and local health departments maintain platforms with information about these issues for patients and caregivers.<sup>19</sup> Our stakeholders believe that Alzheimer's disease patients and their caregivers could benefit from a more unified platform that streamlines all the information and resources available to them. We urge HHS to undertake a review of its current Alzheimer's disease-related resources and consolidate the relevant information for patients and caregivers into a single online resource portal. This can be done through expansion of an existing federal resource portal. Information that our stakeholders believe could be valuable in such a portal include the following:
  - Resources for long-term care planning and clarification on the long-term care benefits, and eligibility for such benefits, under Medicare fee-for-service, Medicare Advantage, Medicaid, and other relevant federal health care programs;
  - Descriptions of the types of long-term care facilities and care options available to Alzheimer's disease patients, including institutional settings and home- and community-based services;
  - Resources for federal- and state-sponsored caregiver support and training programs;
  - Information about clinical trial enrollment, including links to existing registries and support for patients currently enrolled in clinical trials;

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<sup>16</sup> CMS – PACE Regulations and Guidance: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pacel11c01.pdf>

<sup>17</sup> CMS – Overview of the PACE Application Process: [https://www.cms.gov/Medicare/Health-Plans/PACE/Downloads/PACE\\_Applications\\_February\\_6\\_2019.pdf](https://www.cms.gov/Medicare/Health-Plans/PACE/Downloads/PACE_Applications_February_6_2019.pdf)

<sup>18</sup> CMS – PACE Final Rule: <https://www.govinfo.gov/content/pkg/FR-2019-06-03/pdf/2019-11087.pdf>

<sup>19</sup> Such platforms include the [longtermcare.acl.gov](http://longtermcare.acl.gov), [alzheimers.gov](http://alzheimers.gov), [eldercare.acl.gov](http://eldercare.acl.gov), [nia.nih.gov](http://nia.nih.gov), [medicare.gov](http://medicare.gov), [medicaid.gov](http://medicaid.gov), and the general [acl.gov](http://acl.gov) websites.

- Educational resources about Alzheimer's disease and developments in the process toward a cure and treatment;
- Information on identifying and preventing elder abuse, neglect, and exploitation;
- Material on services and devices to improve patient safety, like GPS and web-based home monitoring services for Alzheimer's disease patients who suffer from wandering or navigational issues.

## **INCREASE THE USE AND EFFECTIVENESS OF COGNITIVE SCREENS**

- 1. Address Research Gaps for Cognitive Screens:** The U.S. Preventive Services Task Force has concluded that evidence regarding the effectiveness of cognitive impairment screening is insufficient to support a recommendation for its routine use. As a result, insurers are not required to cover this service and are also allowed to apply cost sharing if they do. Ensuring that appropriate wrap-around services are provided at the right time in a patient's diagnosis could reduce avoidable hospital and emergency department visits and as a result, potentially mitigate federal health care expenditures.<sup>20,21,22</sup> Thus, it is imperative that research into the potential benefits of improved cognitive screens and other means by which providers diagnose Alzheimer's disease are prioritized by HHS so that a more robust body of literature surrounding their use can be established.
- 2. Encourage Use of Evidence-Based Cognitive Assessment Tools:** One objective of Medicare's annual wellness visit (AWV) is to detect cognitive impairment of an individual, a clear symptom of Alzheimer's disease and related dementias. We ask that CMS recommend the use of an evidence-based cognitive assessment tool during AWVs rather than direct observation.<sup>23</sup> Ensuring the results of such assessments be made available in the beneficiary's electronic health record (EHR) could also aid in care coordination.
- 3. Encourage Use of the Health Risk Assessment (HRA) to Assess Cognitive Function:** Given the relatively low uptake in the AWV,<sup>24</sup> we ask that CMS encourage Medicare Advantage plans to use their HRAs to assess cognitive function and the potential long-term care needs of seniors. Plans are provided significant flexibility in what they include in the HRA. While some plans provide for a cognitive screening, not all plans do. These visits and assessments provide ample opportunity for the identification of cognitive disorders such as Alzheimer's disease, which could lead to more timely coordination of care.

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<sup>20</sup> Hospital and ED Use Among Medicare Beneficiaries with Dementia Varies by Setting and Proximity to Death: <https://pubmed.ncbi.nlm.nih.gov/24711331/>

<sup>21</sup> Potentially Avoidable Hospitalizations Among Medicare Beneficiaries with Alzheimer's Disease and Related Disorders: <https://pubmed.ncbi.nlm.nih.gov/23305822/>

<sup>22</sup> Medicare Expenditures Associated with Hospital and Emergency Department Use Among Beneficiaries with Dementia: <https://pubmed.ncbi.nlm.nih.gov/28301976/>

<sup>23</sup> CMS – MLN Booklet on Annual Wellness Visit: [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AWV\\_chart\\_ICN905706.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AWV_chart_ICN905706.pdf)

<sup>24</sup> Practices Caring for the Underserved Are Less Likely to Adopt Medicare's Annual Wellness Visit: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1130>

## **FOSTER INNOVATION FOR ALZHEIMER'S DISEASE THERAPIES AND DIAGNOSTICS**

- 1. Prioritize Alzheimer's Disease within the Food and Drug Administration's (FDA) Complex Innovative Trial Designs (CID) and Model-Informed Drug Development (MIDD) Programs:** The FDA is currently operating two pilot programs, the CID and MIDD, which aim to increase the efficiency of the clinical trial process for innovative therapies and improve the likelihood of their success throughout the regulatory approval process. In particular, the CID provides opportunities for enhanced dialogue with FDA officials during the trial design process, and the MIDD provides sponsors the chance to collaborate with officials on precise risk-benefit models for the drug.<sup>25,26</sup> We urge HHS to consider the merit of incorporating more Alzheimer's disease therapeutic sponsors into these pilot programs.
- 2. Accelerate Development of Diagnostics:** We encourage the National Institutes of Health and NIA to establish a program akin to the Rapid Acceleration of Diagnostics (RADx) initiative for COVID-19 with the goal of bringing to market an affordable and non-invasive point-of-care diagnostic for Alzheimer's disease. If such an initiative would require legislation, we urge you to work with us on the development and passage of such a law.

## **CLARIFY AND IMPROVE ACCESS TO CERTAIN SERVICES**

- 1. Review the 2014 Qualified Settings Rule for Home- and Community-Based Services:** In 2014, CMS finalized a definition for home- and community-based settings.<sup>27</sup> Stakeholders expressed concern that parts of the rule intended to promote community integration or strengthen facility security are not appropriate for cognitively impaired individuals. One stakeholder expressed concern that the requirement of locks on doors to strengthen privacy can pose a threat to patients with dementia. We urge CMS to review the regulation and issue guidance or best practices to states about how settings that provide services to individuals with Alzheimer's disease can best meet the requirements in the regulation. This can either be achieved through setting-specific policies and practices or through modifications to person-centered service plans.
- 2. Evaluate and Expand Access to CPT Code 99483:** CPT code 99483 reimburses providers for undertaking functional assessments and care planning services for individuals living with cognitive impairment. Unfortunately, the most recent utilization data suggests that only a small fraction of eligible seniors are receiving the benefit.<sup>28</sup> We encourage CMS to conduct education and outreach to increase awareness of and access to the code. Additionally, some stakeholders assert that the documentation requirements for

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<sup>25</sup> FDA - Complex Innovative Trial Designs Pilot Program: <https://www.fda.gov/drugs/development-resources/complex-innovative-trial-designs-pilot-program>

<sup>26</sup> FDA - Model-Informed Drug Development Pilot Program: <https://www.fda.gov/drugs/development-resources/model-informed-drug-development-pilot-program>

<sup>27</sup> CMS - Rule on Medicaid HCBS Setting Requirements: <https://www.federalregister.gov/documents/2014/01/16/2014-00487/medicaid-program-state-plan-home-and-community-based-services-5-year-period-for-waivers-provider>

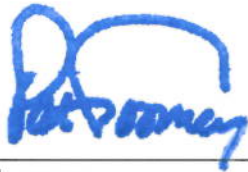
<sup>28</sup> Examining the Adoption of a New Medicare Billing Code for Cognitive Assessments: A Slow But Steady Uptake: <https://healthcostinstitute.org/in-the-news/examining-the-adoption-of-a-new-medicare-billing-code-for-cognitive-assessments-a-slow-but-steady-uptake>



the code's billing are too complex and prone to deficiencies for some providers. We encourage CMS to review the billing requirements for CPT Code 99483 to ensure such requirements are not uniquely onerous. Billing requirements should also require proper documentation in the patient's medical record or EHR.

We thank you for your continued engagement on one of the most pressing health care issues of our time – addressing the scourge of Alzheimer's disease. As we continue our efforts to support the Alzheimer's disease community, we ask that you transmit any legislative recommendations that the Administration may have in the aforementioned areas of care coordination, long-term care accessibility, and the development of a treatment and/or cure for Alzheimer's disease. We look forward to your response and a commitment to improve care delivery for this patient population.

Sincerely,



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Pat Toomey  
Chairman  
Subcommittee on Healthcare  
Senate Committee on Finance



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Debbie Stabenow  
Ranking Member  
Subcommittee on Healthcare  
Senate Committee on Finance

CC: Seema Verma, Administrator, Centers for Medicare & Medicaid Services  
Stephen Hahn, Commissioner, Food and Drug Administration  
Francis Collins, Director, National Institutes of Health  
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